Exhibit G

[19] Patent Office of the People's Republic of China

[51] Int.CI[6]

A61F 2/24
G01M 19/00

[12] Specification of Invention Patent

[21] ZL Patent No. 91104142.7

[45] Authorized Publication Date June 18, 1997

[11] Authorized Publication No. CN 1035153C

[22] Application date 06/26/1991

[21] Application No. 91104142.7

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[56] References

US4546642 US4682491

Examiner 5512

Claims: 2 pages; Specification: 6 pages; Attached Drawings: 6 pages

[54] Title of invention

A prosthetic heart valve fatigue life test device

[57] Abstract

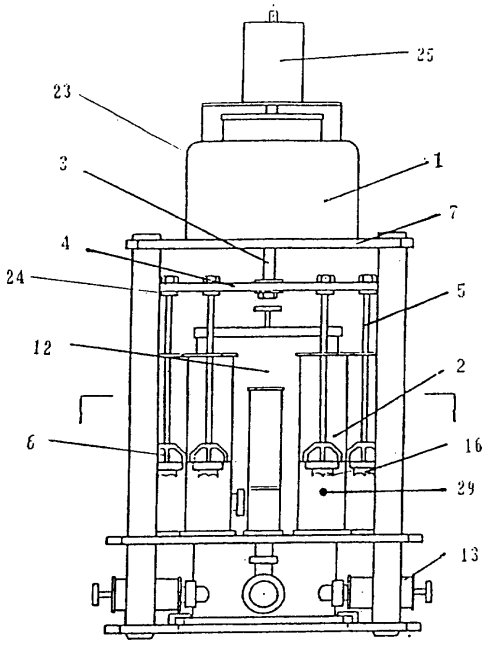
A prosthetic heart valve fatigue life test device.

The present invention proposes that the total load on the valve is used as a monitoring parameter. The drive frequency, amplitude, and valve back pressure are adjusted so that the valve load waveform after acceleration is close to the load waveform at 72 beats/min.

The device of the present invention has the three portions of the drive, main body, and monitoring. The main body portion consists of a linear motor, a test section, and a circulation loop. The linear motor is located at the top of the device, and a drive signal drives the linear motor to drive the reciprocating motion of the link rods and valves in the test sections through the spindle disc.

The monitoring portion consists of the valve load, displacement, and pressure transducers.

This device has a compact and reasonable structure, can continuously work stably for a long time, and has good sealing, no noise, and low energy consumption.



1. A prosthetic heart valve fatigue life test device is characterized in that the device consists of a main body portion, a drive portion, and a monitoring portion.

Its main body comprises: linear motor (1), test section (2), circulation loop (30), main shaft (3), spindle disc (4), link rod (5), and valve frame (6). The linear motor (1) is located on the upper part of the device, i.e., the upper part of the frame (7). The linear motor shaft is integral with the main shaft (3), and the lower end of the main shaft (3) is fixed to the spindle disc (4). Each test section (2) has a link rod (5) and a valve frame (6). The upper end of the link rod (5) is connected to the spindle disc, the valve (16) is installed on valve frame (6) at the lower end of link rod (5), and the valve test sections (2) are independently distributed symmetrically with the main shaft (3) at the center.

The drive portion is the power source of the device, comprising a power supply (8), an arbitrary waveform generator (9), and a DC power amplifier (10). The drive signal drives the linear motor (1), through the main shaft (3) and the spindle disc (4) to drive the reciprocating motion of the link rod (5) and valve frame (6) in the test section (2).

The monitoring portion comprises a valve load measurement, a valve displacement measurement, and a valve back pressure measurement. The valve load test is performed using a strain-based force transducer (24), which is mounted between the link rod (5) and the spindle disc (4). The valve displacement measurement is performed using a photoelectric displacement transducer (25), which is mounted at the upper end of the linear motor (1). The valve back pressure is measured using a blood pressure transducer (29).

2. A prosthetic heart valve fatigue life test device in Claim 1

is characterized in that two force transducers (24) with consistent performance are installed between the two symmetrical link rods (5) and the spindle disc (4). One of the two symmetrical valve frames (6) is installed with the tested valve (16), and the other is not fitted with a valve (16). At different frequencies, the output of the two force transducers (24) is subtracted to obtain the change curve of the total load received by the valve (16).

3. A prosthetic heart valve fatigue life test device of Claim 1 is characterized in that said circulation loop is a two-unit two-parameter circulation loop (30) that comprises air chamber C_1 (11), a needle valve damper R_1 (13), a reservoir tank (17), large air chamber C_2 (12), and damper R_2 (14). C_1 and R_1 correspond to the respective test sections (2). The large air chamber C_2 (12) is located above a perforated separator (18) in the reservoir tank (17), and R_2 (14) is located above the concentric cylinder of the reservoir tank (17) and is adjustable.

4. A prosthetic heart valve fatigue life test device of Claim 1 is characterized in that said linear motor (1) consists of a motor shaft, bobbin (19), coil (20), guide magnet (21), and permanent magnet (22), and its exterior has a stainless steel cover (23). The whole moving part is a titanium alloy material, using a centered orientation.

5. A prosthetic heart valve fatigue life test device of Claim 1 is characterized in that the drive system of the device is equipped with a 36-volt battery and a power supply (8) to ensure the continuous normal operation of the drive system when a sudden power failure occurs.

6. A prosthetic heart valve fatigue life test device in Claim 1 is characterized in that the device has an observation system, and the movement of the leaflets can be observed by the mirror (26), the strobe light (28), and the observation tube (27).

A prosthetic heart valve fatigue life test device

The technical field to which the present invention belongs is biomechanical measurement technology.

Current international and domestic state of the art for the present invention:

The heart of the human body is the center of the blood circulation system, which provides a rhythmic contraction and dilation to push blood to flow through the blood vessels. The human heart is composed of four chambers, with valves between the ventricle and the atrium and between the ventricle and the outlet. Heart valves are simple stop valves that passively open and close as the heart relaxes and contracts. Heart valves can be damaged by various congenital defects or by rheumatic disease, which impairs normal one-way reverse function. With the development of biomedical engineering, artificially manufactured heart valves can now be used to replace the diseased valves and restore the patient's ability to work. Therefore, the performance and longevity of prosthetic valves directly affect the safety of patients. Due to the long cycles of animal and clinical experiments, the evaluation and comparison of the fatigue life and mechanical performance of prosthetic heart valves are mainly achieved by in vitro simulation test devices. According to relevant data at home and abroad, due to calcification, perforation, and leaflet tearing of biological valves and due to wear, fracture, and jamming of mechanical valves, death and re-operation were the results for a great proportion of valve failures. In particular, due to the nature of the material, the structural design, and the manufacturing process, the fatigue life problem is even more prominent, which has become the main problem affecting the development of the bio-valve.

The in vitro accelerated simulated fatigue life test of prosthetic heart valves can greatly shorten the study cycle and can accumulate a significant amount of valve durability data over a long period of time. The advantages and disadvantages of the structural design, material selection, and treatment process of prosthetic heart valves can be identified early in the development process. Some scholars have been engaged in this research as early as the 1960s and have successively established simulation test devices with different structures. Most representative of these are R.E. Clark and M.W. Swanson's test benches, H. Reul's "rotary" test devices, and the fatigue life test devices of the United Kingdom's Rowan Ash company. However, the circulatory systems of these simulated test devices are relatively simple, and only the trans-valve pressure differential is controlled to be similar to the physiological conditions. This also does not take into consideration the stress changes generated at high frequencies after acceleration. The forces experienced by valves under acceleration are much greater than those experienced by movements under normal physiological conditions, so the measurement of the fatigue life of prosthetic heart valves on these simulation devices is much smaller than the actual life in the body. The data obtained from fatigue tests on the same valve on different simulation devices can also have big differences. Most of the existing simulated test devices are mechanical transmission methods, with poor wear resistance and high noise. The life of the device itself is short, so it cannot work continuously for a long time.

To solve the problems in the existing prosthetic valve fatigue life test, the present invention invents a prosthetic heart valve fatigue life test device. Its prominent point is that the load experienced after the prosthetic heart valve is accelerated is similar to the physiological conditions in vivo so that the results of the in vitro artificial conditions test can reflect the condition in vivo to a certain extent and predict the working condition and life of the prosthetic heart valve in vivo.

The basic point of the present invention is: Using the total load on the valve as the monitoring parameter, i.e., by adjusting the compliance and impedance of the circulation loop (30), the drive waveform, frequency, and amplitude are adjusted so that the total load experienced by the prosthetic heart valve after acceleration is similar to the total load experienced under physiological conditions (72 beats/min (see Fig. 6). The device of the present invention comprises a main body portion, a drive portion, and a monitoring portion (see Fig. 1). The main body portion consists of a linear motor (1), test section (2), circulation loop (30), main shaft (3), spindle disc (4), link rod (5), and valve frame (6). The linear motor (1) is located on the upper part of the device, i.e., above the frame (7). The linear motor shaft is integral with the main shaft (3), and the lower end of the main shaft (3) is fixed to the spindle disc (4). The circulation loop (30) employs a two-unit two-parameter model. Each of the six test sections is independent, and within each test section there is a link rod (5) and valve frame (6). The valve test sections (2) are symmetrically distributed in pairs with the main shaft (3) as the center. The drive portion is the power source of the device and includes a power supply (8), an arbitrary wave generator (9), and a DC power amplifier (10). The linear motor (1) is driven by the drive signal, through the main shaft (3) and the spindle disc (4) to drive the reciprocating motion of the link rod (5) and valve frame (6) in the test section (2) to open and close the test valve. The monitoring portion comprises: A valve load measurement transducer mounted between the spindle disc (4) and the link rod (5); a pressure measurement transducer (29) mounted on the wall of the test section (2) below the valve, and a displacement monitoring transducer (25) mounted on the upper end of the linear motor shaft.

Compared with the state of the art, the test device for the fatigue life of the prosthetic heart valve of the present invention has the following characteristics:

1. The concept is novel, the design is refined, the parameters are reasonable, the device is compact and symmetrical, the test device and the monitoring instruments are integrated, its portability is convenient, and the footprint is small.

2. The circulation loop (30) and the test section (2) have a reasonable structure, can simulate the compliance and impedance of the arterial system, greatly reduce the occurrence of the water hammer effect, have good sealing performance, provide easy valve replacement, and are easy to install and unpack so as to facilitate observation.

3. The linear motor (1) and main shaft (3) are located above the unit so they do not create any conflicts in sealing and friction caused by a lower drive, are noise-free, and have low energy consumption.

4. Monitoring of valve motion transforms into monitoring displacement, frequency, and pressure for easy automatic control.

5. Six symmetrical valves (16) are tested simultaneously and driven by the same drive shaft, so their amplitude and frequency are exactly the same. As long as the adjustment of the valve back pressure is the same, the valve load is the same, so as to facilitate comparison.

6. The total valve load can be adjusted by changing the drive frequency, amplitude, and valve back pressure to bring the total load in the accelerated operating state close to physiological conditions.

7. The entire device has no mechanical transmission components, the friction is very small, the durability is good, the corrosion resistance is good, and the circulation frequency can reach 2,000 beats/min under fully open and closed conditions of the valve, that is, above 33 Hz. It can work reliably and continuously for a long time.

8. The unit is equipped with batteries and a power source to continue operation in the event of a power outage to the power grid.

Attached Drawings:

Fig. 1.A block diagram of a prosthetic heart valve fatigue life test device.

Fig. 2.A schematic view of the main body structure of a prosthetic heart valve fatigue life test device.

Fig. 3.Schematic top view of main body structure.

Fig. 4.Schematic diagram of circulation loop.

Fig. 5.Schematic diagram of a linear motor structure.

Fig. 6. Load waveform at 72 beats/min.

Fig. 7. Schematic diagram of observation system structure.

A detailed structure of the apparatus of the present invention is described below with reference to the attached drawings.

The present invention indicates that in addition to the trans-valve differential pressure, inertial forces should also be considered as forces acting on the valve at high frequencies after acceleration, with the total force being:

$F = Fm, F_q, F_{\Delta P}$

Fm—Inertial force caused by the inertial mass of the moving parts of the valve.

$F_{\Delta P}$—The force by which the trans-valve pressure differential acts on the valve.

F_q—The force by which fluid inertia acts on the valve.

The inertial force is proportional to the square of the frequency of motion, i.e. $(Fm + F_q) \propto f^2$, with f as the heart rate. Inertial forces Fm and Fq are small at physiological frequencies, i.e., low frequencies, and are small relative to the trans-valve pressure differential. The physiological system works optimally with pulsating flow, having a good balance of inertia and compliance. When accelerated, the forces caused by the inertia and fluid inertia of the moving parts of the valve will increase dramatically, with the inertial forces and the trans-valve pressure differential together forming the total load on the valve. On the test devices of the state of the art, only the trans-valve pressure differential is taken into consideration as being made similar to physiological conditions, so it is necessary to make the valve load high after acceleration. It will be quickly damaged due to excessive force. Therefore, the test result of the valve fatigue life is far less than the actual life in the body. This problem actually involves how to ensure that the load on the prosthetic heart valve structure during the in vitro acceleration test is similar to the load on the prosthetic heart valve under physiological conditions in the body. In order to make the distribution of maximum stress similar to the maximum stress distribution of the prosthetic heart valve under physiological conditions, we can adjust the compliance and impedance of the circulation loop system, change the flow rate through the valve and the trans-valve pressure differential, and select the appropriate drive waveform to drive the linear motor to move according to a certain waveform, frequency, and amplitude so that the opening and closing motion of the heart valve is close to the physiological conditions and so that the movement pattern of the system after acceleration can be close to the normal physiological conditions. The valve back pressure waveform is close to the aortic pressure waveform under normal physiological conditions, and no water strike is produced when the valve is opened and closed.

A prosthetic heart valve fatigue life test device of the present invention, which is composed of a drive portion, a main part, and a monitoring part (see Figure 1). The drive portion thereof is a power source consisting of a power supply (8), an arbitrary wave generator (9), and a DC power amplifier (10). The main part includes the linear motor (1) test section (2), circulation loop (30), main shaft (3), spindle disc (4), link rod (5), and valve frame (6) (see Figure 2. 3). The circulation loop (30) uses a two-unit two-parameter model (see Fig. 4), which consists of air chambers C_1 (11) and C_2 (12), dampers R_1 (13) and R_2 (14), and test sections (2). The valve test sections (2) are independent, and the test sections (2) are paired and distributed symmetrically with the main shaft (3). The device uses six valve test sections. The upper end of the link rod (5) is coupled with the spindle disc (4). The valve (16) is mounted on the valve frame (6) at the lower end of the link rod (5). The required waveform is generated by an arbitrary waveform generator (9). After being amplified by the DC power amplifier (10), the waveform drives the linear motor (1), through the main shaft (3) and the spindle disc (4) to drive the link rod (5). The valve (16) opens under fluid inertial action when the valve frame (6) moves up. The valve (16) closes due to fluid resistance as the valve frame (6) moves down. This

also pushes the liquid down. The liquid flows from each test section (2) to its respective corresponding air chamber C_1 (11) and needle valve damper R_1 (13) and then flows together into the liquid storage tank (17). The liquid storage tank (17) has a large air chamber C_2 (12), and there is a perforated separator (18) below it to prevent water waves. The liquid is divided and diverted back to each test section through the adjustable damper R_2 (14). The valve back pressure, i.e., the trans-valve pressure differential, is adjusted through the damper R_1 (13) and can be varied from 0 to 100 mg Hg, which can meet the physiological range. The waveform generator (9) can provide an arbitrarily selected drive waveform to ensure the movement of the linear motor (1) so that the opening and closing movements of the heart valve are close to physiological conditions. By adjusting the valve back pressure and the frequency, amplitude, and waveform of the drive signal, the total load curve on the valve (16) under accelerated operation is brought close to the total load curve at normal heart rate, i.e., the load waveform at 72 beats/min heart rate (see Fig. 6). The linear motor (1) is mounted above the frame (7) (see Fig. 2). In terms of its structure (see Fig. 5), it consists of the motor shaft (3) (the motor shaft and the main shaft are integrated), the bobbin (19), the coil (20), the guide magnet (21), the permanent magnet (22), and its outer stainless steel cover (23). The whole moving part is made of titanium alloy material, so it is lightweight, has a wide frequency range, good fatigue resistance, and uses a centered orientation. It has small radial force, low friction, low energy consumption, smooth motion, and no noise.

The monitoring system comprises the three parts of a valve load measurement, a valve displacement measurement, and a valve back pressure measurement.

The valve load measurement is a change curve of the load the valve (16) is subjected to during motion as measured with a strain-based force transducer (24). The transducer (24) is mounted at the junction of the valve link rod (5) and the spindle disc (4) (see Fig. 2). The force on valve (16) is transmitted to the force transducer (24) through the link rod (5). The output of the force transducer (24) is the sum of the load size on valve (16) and the link rod (5), the valve frame (6). In order to obtain the load received by the valve (16), the load of the link rod (5) and the valve frame (6) must be subtracted. For this reason, we first installed it without the valve (16) for the adjustment, installing two force transducers (24) with consistent performance on the two link rods (5) that are symmetrical. At different frequencies, the dynamic load of the valve frame (6) and the link rod (5) was measured. Due to its complete symmetry, the post-movement load was zero, and then the tested valve (16) was installed on one valve frame (6) and the other without the valve (16). After the output of the two force transducers (24) at different frequencies was subtracted, the curve of the load received by the valve (16) was obtained. Making the load during the accelerated operation close to the normal heart rate is achieved by adjusting the valve back load and drive signal. This force transducer (24) is very convenient to install and uninstall. When measuring force, the transducer (24) is installed. After the whole machine is adjusted, the force transducer (24) is removed, and the device will operate normally.

The pressure measurement uses a blood pressure transducer (29). A pressure measurement hole is opened on the side wall of the test section (2) on the back side of the valve (16), and the valve back pressure change is measured through a small medical three-way valve connected to the test section (2). Using a small medical three-way valve, the blood pressure transducer (29) can be connected to the test section (2) during pressure measurement. When pressure is not being measured, it is opened to atmosphere and zeroed.

Detection of displacement signal: The motion of the linear motor (1) is measured by the displacement transducer (25). The displacement transducer (25) is mounted at the upper end of the linear motor (1) (see Fig. 2). The photoelectric principle is adopted to detect changes in displacement using the principle that the current generated by the photosensitive element is proportional to the area of light. The line light source emitted by the slit light source is obstructed by a part of the shaft end of the linear motor (1) and irradiated onto the light-sensitive element. When the linear motor (1) is moved on and off the shaft end, the light flux received by the light-sensitive element changes, which is directly proportional to the amplitude of the reciprocating movement of the linear motor (1). The change in current generated by the light-sensitive element reflects the change in the amplitude of the linear motor (1). The displacement transducer (25) has a simple structure, no mechanical transmission parts, and has no wear, making it suitable for long-term continuous operation.

The test device for the fatigue life of the prosthetic heart valve of the present invention is accelerated under near-physiological conditions of load, under which the valve (16) is fully opened and closed in each cycle. There is an observation system (see Fig. 7). The mirror (26) is installed below the valve test section (2), and the strobe light (28) is used to irradiate the valve (16). When the flash frequency of the strobe light (28) is adjusted to have a certain difference from the rate of valve movement, it can be clearly seen through the observation tube (27) that the valve (16) is slowly opened and closed. Whether it is fully opened and closed, whether the valve (16) is damaged or deformed, whether the leaflets are fluttering, and other motions are recorded through the video recording system.

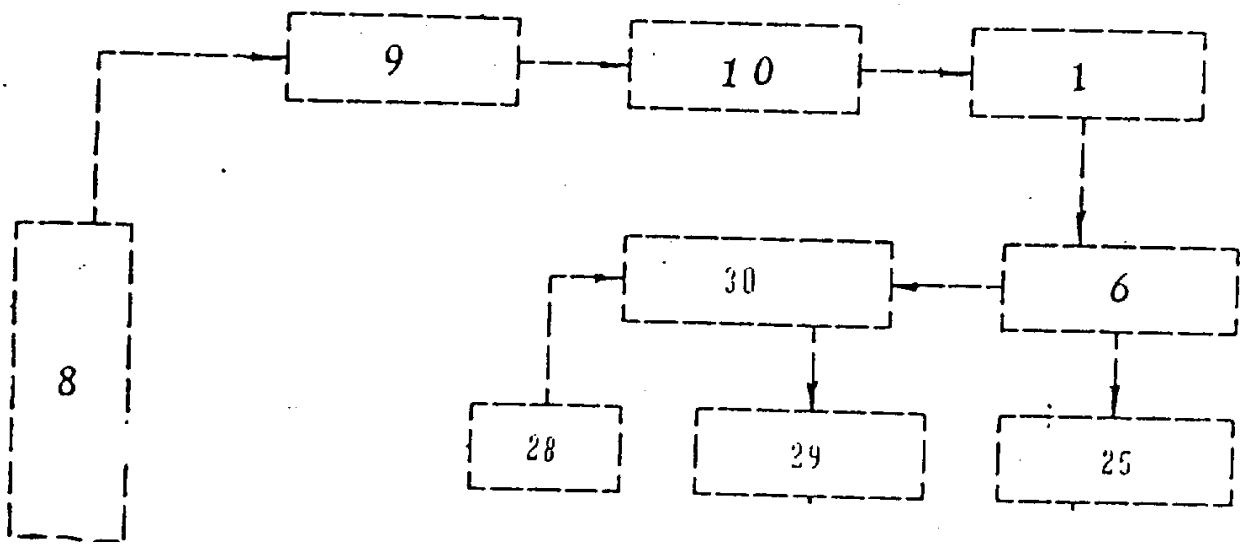


Fig. 1

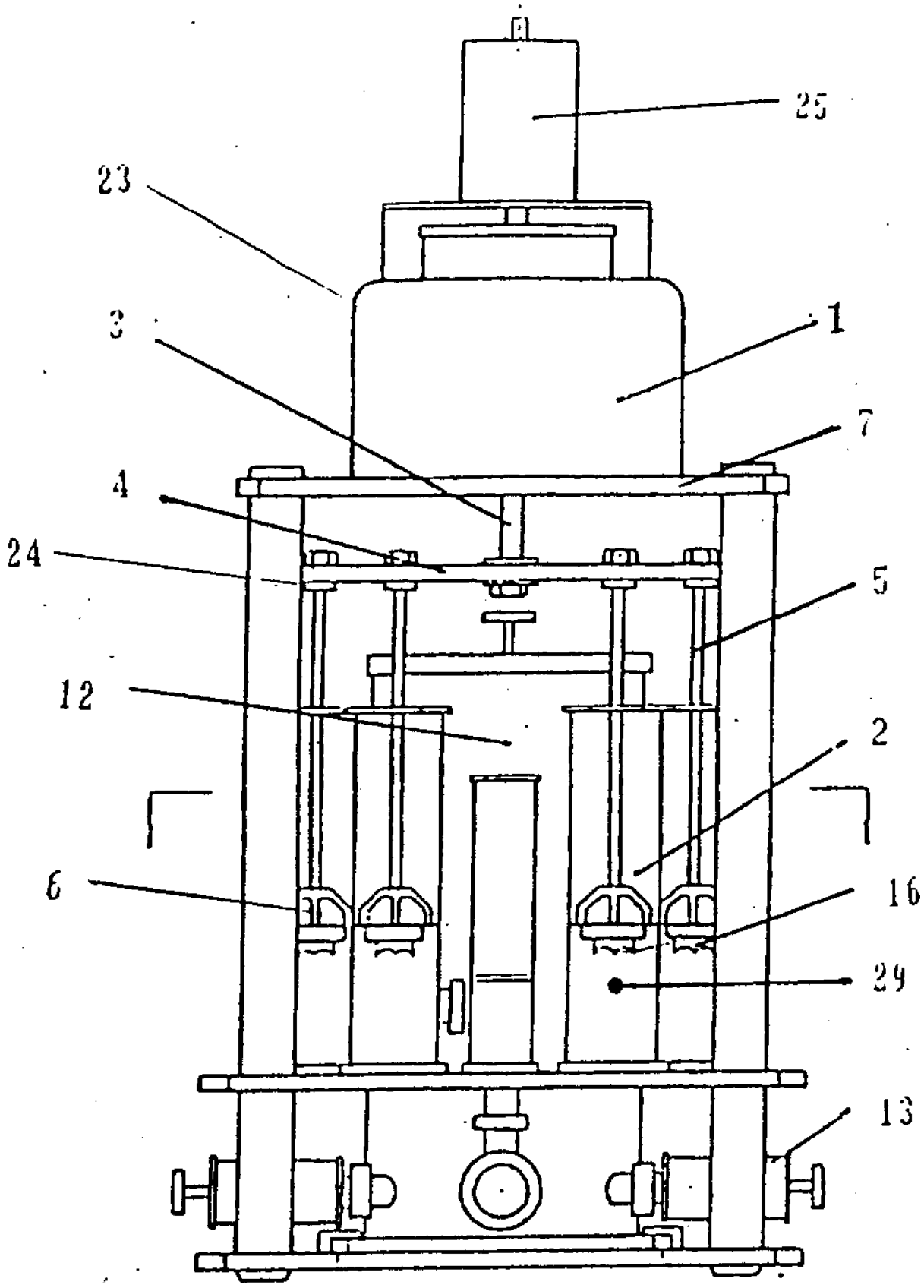


Fig. 2

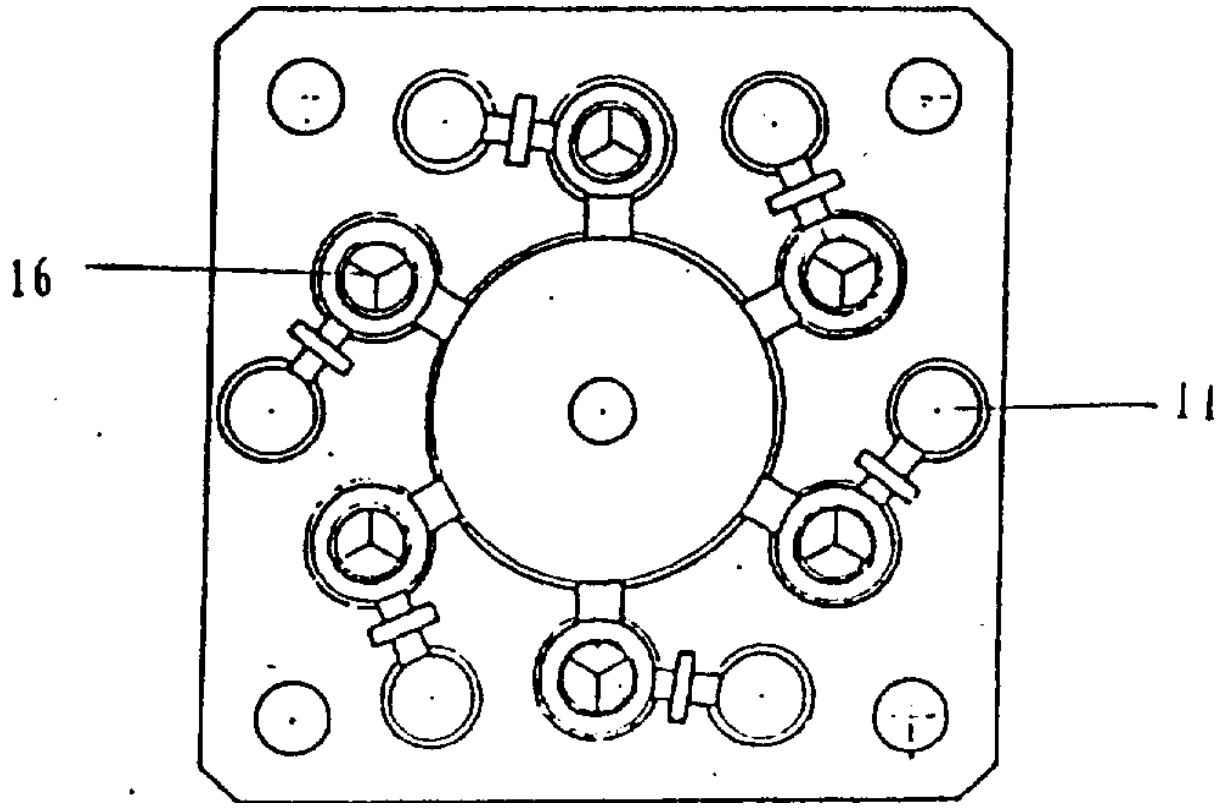


Fig. 3

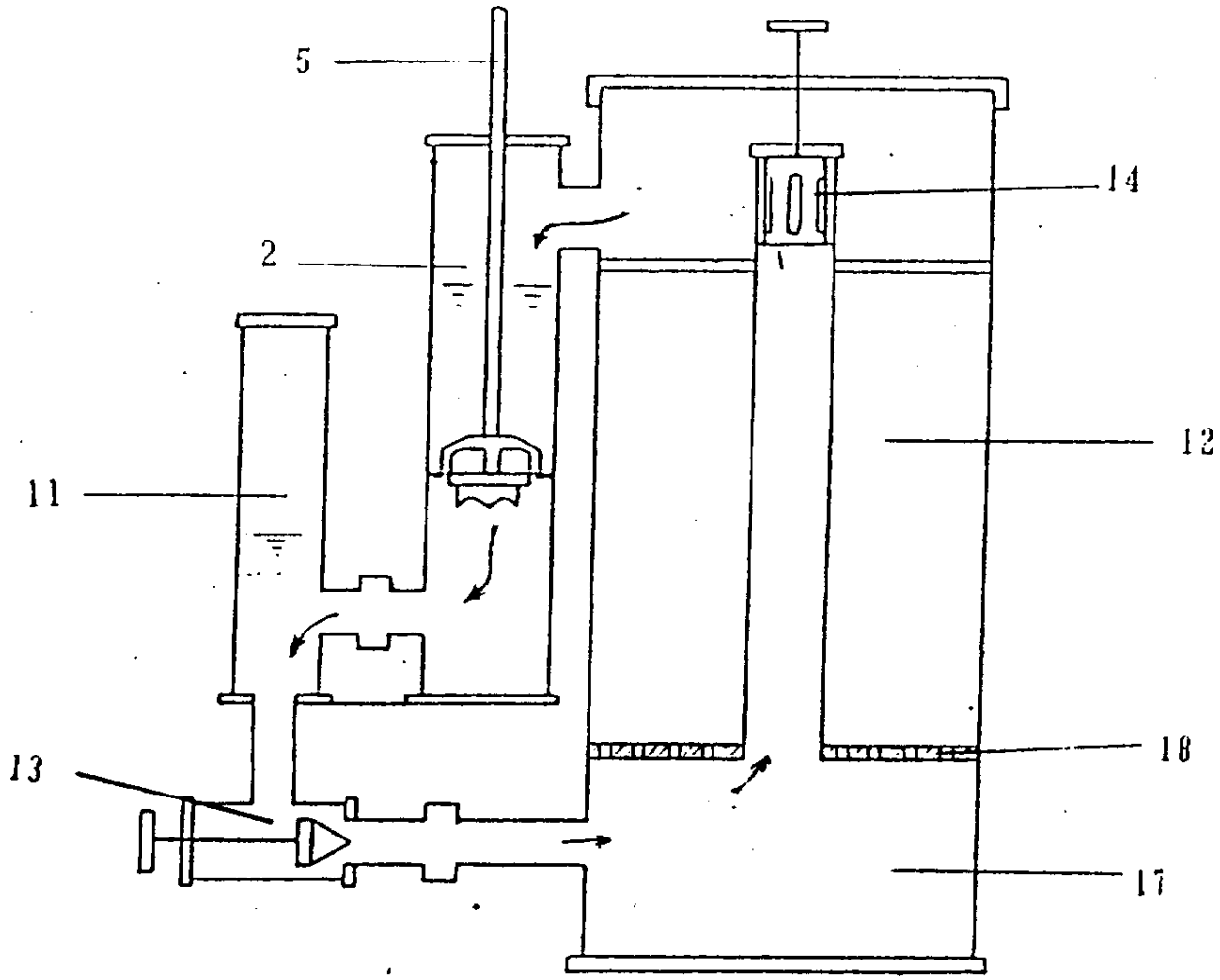


Fig. 4

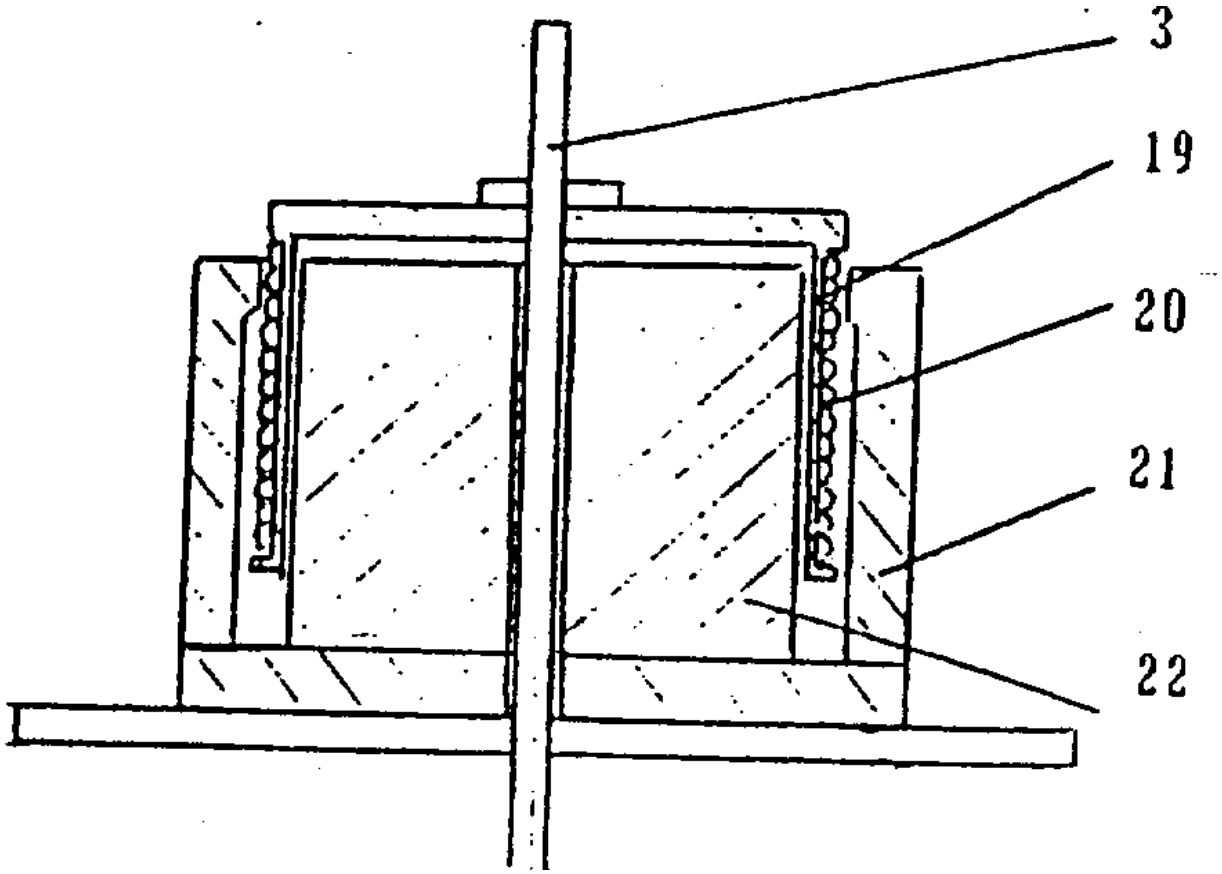


Fig. 5

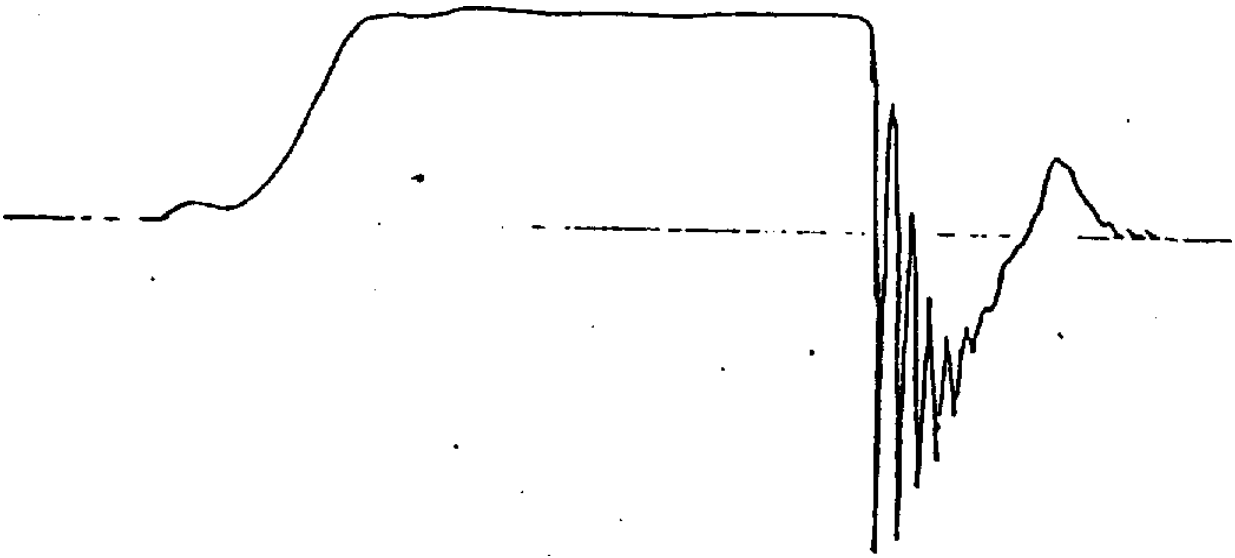


Fig. 6

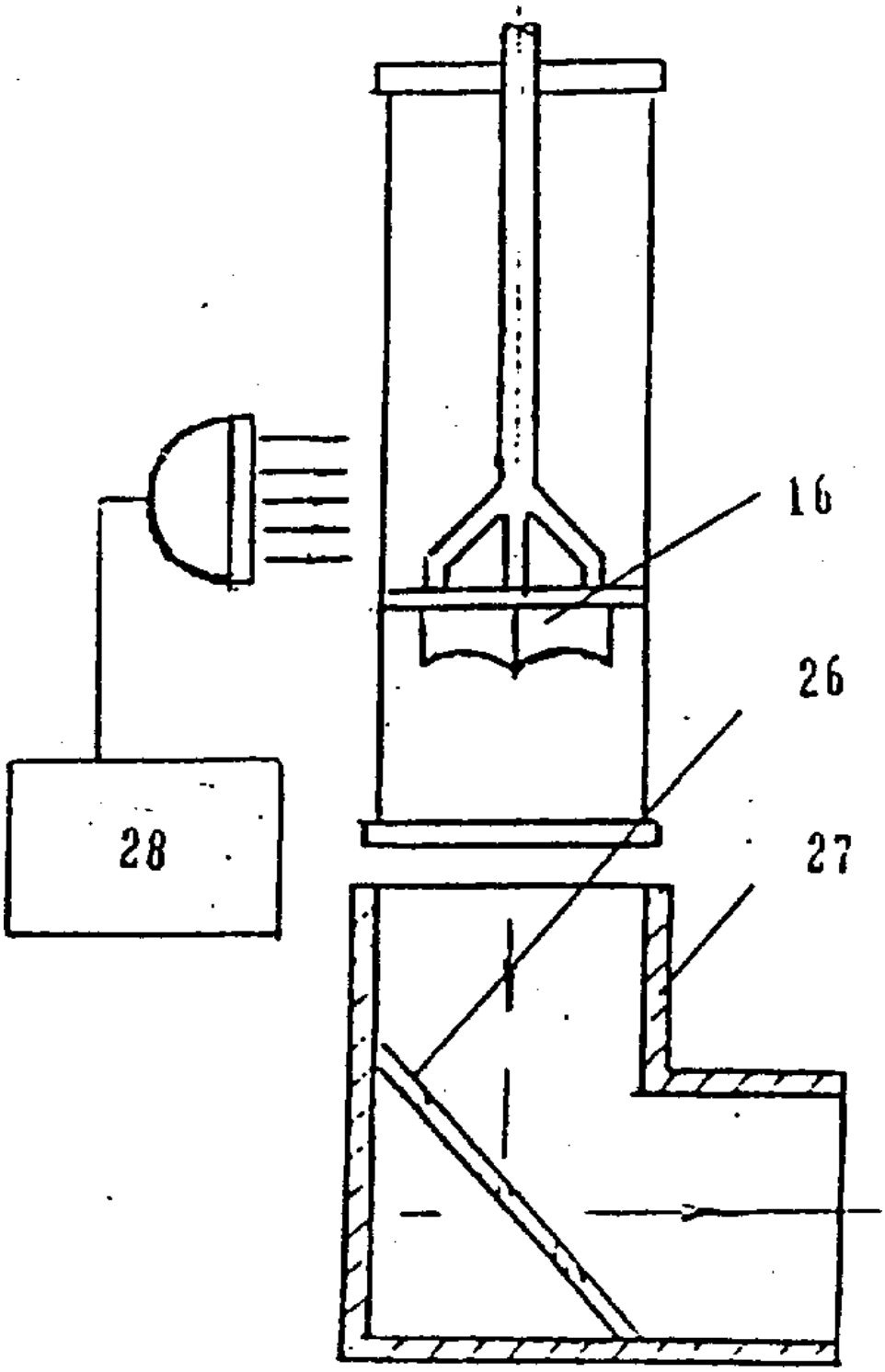
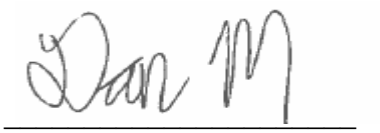


Fig. 7

TRANSPERFECT

City of New York, State of New York, County of New York

I, Dan McCourt, hereby certify that the document "**cn1035153c**" is, to the best of my knowledge and belief, a true and accurate translation from Chinese into English.



Dan McCourt

Sworn to before me this
May 1, 2023

Signature, Notary Public

Stamp, Notary Public

[19] 中华人民共和国专利局

[51] Int. Cl⁶
A61F 2/24
G01M 19/00

[12] 发 明 专 利 说 明 书

[21] ZL 专利号 91104142.7

[45] 授权公告日 1997年6月18日

[11] 授权公告号 CN 1035153C

[22] 申请日 91.6.26

[21] 申请号 91104142.7

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[56] 参考文献
US4546642
US4682491

审查员 5512

权利要求书 2 页 说明书 6 页 附图 6 页

[54] 发明名称

一种人工心脏瓣膜疲劳寿命试验装置

[57] 摘要

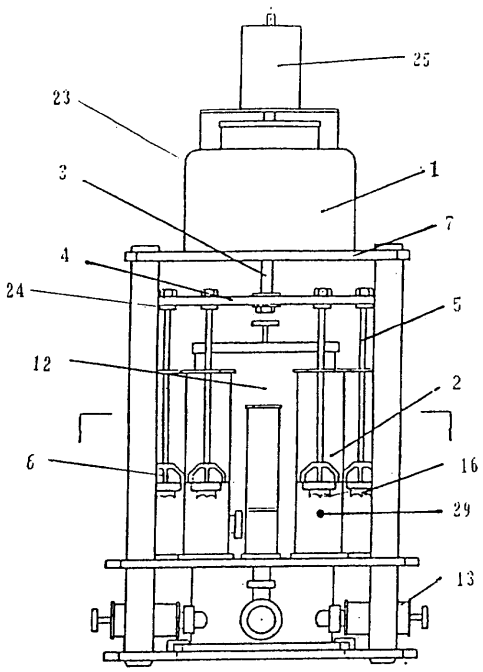
一种人工心脏瓣膜疲劳寿命试验装置。

本发明提出瓣膜上的总载荷做为监控参数。调节驱动频率，振幅和瓣后压力，使其加速后瓣膜载荷波形接近72次/分心率下载荷波形。

本发明的装置，它有驱动，主体，监测三部分。主体部分由直线电机，实验段和循环回路组成。直线电机位于该装置上方，由驱动信号驱动直线电机经主轴盘带动联杆和瓣膜在实验段中往复运动。

监测部分由瓣载、位移和压力传感器组成。

本装置结构紧凑合理，能连续长期稳定工作，密封性好，无噪声，能耗低。



1. 一种人工心脏瓣膜疲劳寿命试验装置，其特征在于该装置由主体部分，驱动部分和监测部分组成，

其主体部分包括，直线电机1，实验段2，循环回路30，主轴3，主轴盘4，联杆5，瓣膜架6，直线电机1位于该装置的上部即支架7的上面，直线电机轴与主轴3为一体，主轴3的下端与主轴盘4固连，而每个实验段2内都有一个联杆5和瓣膜架6，联杆5的上端与主轴盘连接，瓣膜16安装在联杆5下端的瓣膜架6上，瓣膜实验段2各自独立都以主轴3为中心对称分布；

驱动部分是本装置的动力源，包含有电源8，任意波发生器9和直流功率放大器10，由驱动信号驱动直线电机1经主轴3，主轴盘4带动联杆5和瓣膜架6在实验段2内往复运动；

监测部分包括瓣载测量，瓣膜位移测量和瓣后压力测量，瓣载测试是用应变式测力传感器24，该传感器安装在联杆5与主轴盘4之间，瓣膜位移测量是用光电式位移传感器25，安装在直线电机1的上端，瓣后压力用血压传感器29测量。

2. 按照权利要求1所说的一种人工心脏瓣膜疲劳寿命试验装置其特征在于将两个性能一致的测力传感器24，安装在对称的两个联杆5与主轴盘4之间，两个对称的瓣膜架6其中一个瓣膜架6安装被测瓣膜16，另一个不装瓣膜16，在不同频率时两个测力传感器24输出相减即得到瓣膜16所受总载荷的变化曲线。

3. 按照权利要求1所说的一种人工心脏瓣膜疲劳寿命试验装置，其特征在于所说的循环回路是二单元二参数循环回路30，它包括气容$C_1$11，针阀型阻尼器$R_1$13，储液罐17，大气容$C_2$12，阻尼器$R_2$14，C_1，R_1与各自的实验段2对应，大气容$C_2$12位于储液罐17带孔隔板18的上方，$R_2$14位于储液罐17同心圆筒的上方且可调。

4. 按照权利要求1所说的一种人工心脏瓣膜疲劳寿命试验装置，其特征在于所说的直线电机1，它由电机轴，线圈骨架19，线圈20，导磁体21，永久磁体22组成，其外部有不锈钢罩23，整个运动部件为钛合金材料，采用中心导向。

5. 按照权利要求1所说的一种人工心脏瓣膜疲劳寿命试验装置，其特征在于该装置的驱动系统备有36伏蓄电池和电源8，当突然断电时保证驱动系统连续正常工作。

6. 按照权要求1所说的一种人工心脏瓣膜疲劳寿命试验装置，其特征在于该装置上有观察系统，由反射镜26，频闪灯28，观察筒27，可以观察瓣叶运动情况。

一种人工心脏瓣膜疲劳寿命试验装置

本发明所属技术领域为生物力学量测技术。

本发明国际、国内现有技术情况：

人体心脏是血液循环系统的中枢，它以节律性的收缩、舒张，推动血液在血管内流动。人的心脏由四个腔室组成，在心室和心房之间，心室与出口管道之间都有瓣膜，心脏瓣膜是简单的止逆阀，随着心脏的舒张、收缩而被动地开闭。由于各种先天性的缺陷或由于风湿性疾病的侵袭，心脏瓣膜会受到损害而丧失正常的单向止逆的功能。随着生物医学工程的发展，现在已可以用人工制造的心瓣置换病变瓣膜，使病人恢复劳动能力。因此人工瓣膜性能的好坏，寿命的长短，直接影响病人的安危。由于动物实验和临床实验的周期很长，评价和比较人工心瓣的疲劳寿命和力学性能主要靠体外模拟实验装置来实现。据国内、外有关资料，由于生物瓣的钙化，穿孔，瓣叶撕裂，由于机械瓣的磨损，断裂和卡住等原因，所造成的死亡和重新手术占了瓣膜失效中很大一部分。尤其是生物瓣，由于材料性质，结构设计和制造工艺等原因，它的疲劳寿命问题更为突出，成了当前影响生物瓣发展的主要问题。

人工心脏瓣膜体外加速模拟疲劳寿命试验，可以大大缩短研究周期，可以在一段不长的时间内积累可观数量的瓣膜耐久性资料。在研制过程中能及早鉴别人工心瓣的结构设计、材料选择和处理工艺的优劣。早在60年代就有人从事这方面的研究工作，陆续建立了结构各异的模拟实验装置，较有代表性的是R.E Clark和M.W Swanson的实验台，H.Reul的“转盘式”实验装置及英国的Rowan Ash公司的疲劳寿命实验装置。但是这些模拟实验装置的循环系统比较简单，只控制跨瓣压差与生理条件相似，而没有考虑在加速后高频情况下产生的应力变化。瓣膜在加速情况下所受的力比正常生理条件下运动所受的力大的多，因此这些模拟装

置上的人工心脏瓣膜疲劳寿命测量结果，大都远远小于在体内的实际寿命，而且在不同模拟实验装置上对同一瓣膜进行疲劳实验所得数据也有很大差异。现有的模拟实验装置多数都是机械传动方式，耐磨性差，噪声大，装置本身的寿命较短，无法长时间连续工作。

本发明是为了解决现有人工瓣膜疲劳寿命试验中存在的问题，而发明的一种人工心脏瓣膜疲劳寿命的试验装置，其突出之点是使人工心瓣加速后所受载荷与体内生理条件相似，这样使体外人工条件下实验的结果，能在一定程度上反映体内的情况，预测人工心瓣在体内的工作情况和寿命。

本发明的基本点是：以瓣膜上的总载荷作为监测参数，即通过调节循环回路30的顺应性和阻抗，调节驱动波形，频率和振幅，使加速后人工心瓣所受的总载荷与生理条件下(72次/分)所受总载荷(图6)相似。本发明的装置包括主体部分，驱动部分和监测部分(见图1)。主体部分由直线电机1，实验段2，循环回路30，主轴3，主轴盘4，联杆5和瓣膜架6组成。直线电机1安置在该装置的上部即支架7的上面，电机轴与主轴3为一体，其下端与主轴盘4相连。循环回路30采用二单元二参数模型。六个实验段各自独立，每个实验段之内都有一个联杆5和瓣膜架6。瓣膜实验段2成对的以主轴3为中心对称分布。驱动部分是本装置的动力源，包含有电源8，任意波发生器9和直流功率放大器10。由驱动信号驱动直线电机1经主轴3，主轴盘4带动联杆5和瓣膜架6在实验段2内往复运动使被测瓣膜开闭。监测部份包括：安装于主轴盘4和联杆5之间的瓣载测量传感器；安装于瓣膜下方实验段2壁上的压力测量传感器29和安装于直线电机轴上端的位移监测传感器25。

本发明人工心脏瓣膜疲劳寿命的试验装置与现有技术比较，有以下特点：

1.构思新颖，设计精细，参数合理，装置结构紧凑而对称，实验机

与监控仪器整套装置合为一体，移动方便，占地面积小。

2. 循环回路30及实验段2结构合理，能模拟动脉系统的顺应性和阻抗，大大减少产生水击现象，密封性能好，换瓣容易，装拆方便，便于观察。

3. 直线电机1及主轴3位于装置的上方，因此不会产生由于下方驱动带来的密封和摩擦的矛盾，无噪声，能耗低。

4. 对瓣膜运动的监测转化为监测位移、频率和压力，容易实现自动控制。

5. 同时测试对称的6个瓣膜16，由同一驱动轴驱动，因此它们的振幅，频率完全相同，只要瓣后压力调节相同，瓣载就相同，便于比较。

6. 瓣膜总载荷可通过改变驱动频率，振幅，瓣后压力来调节，可以使加速运行状态下总载荷接近生理条件。

7. 整个装置没有机械传动部件，摩擦力很小，耐久性能好，耐腐蚀性能好，保证瓣膜全开、全闭条件下，循环频率可达2000次/分，即33Hz以上。可以长期连续可靠地工作。

8. 本装置备有蓄电池和电源可以在电网断电情况下继续工作。

附图：

图1. 一种人工心脏瓣膜疲劳寿命试验装置框图。

图2. 一种人工心脏瓣膜疲劳寿命试验装置主体结构正视示意图。

图3. 主体结构俯视示意图。

图4. 循环回路示意图。

图5. 直线电机结构示意图。

图6. 72次/分心率下的载荷波形。

图7观察系统结构示意图。

下面结合附图说明本发明装置的详细结构。

本发明指出在加速后高频情况下作用在瓣膜上的力，除跨瓣压差外

还应考虑惯性力，其总作用力为：

$F = Fm + F_q + F_{\Delta P}$

Fm——瓣膜运动部件的惯性质量引起的惯性力。

$F_{\Delta P}$——跨瓣压差作用在瓣膜上的力。

F_q——流体惯性作用在瓣膜上的力。

而惯性力与运动频率的平方成正比，即$(Fm + F_q) \propto f^2$，f是心率。在生理频率下即低频时惯性力Fm和Fq很小，相对于跨瓣压差是一个很小的量。生理系统是在脉动流最佳状态工作，其惯性和顺应性处于很好的平衡。当加速后，瓣膜运动部件的惯性和流体惯性引起的作用力将急剧增加，惯性力和跨瓣压差一起构成瓣膜上的总载荷。而现有技术的实验装置上，只考虑跨瓣压差与生理条件下相似，所以必然使瓣膜在加速后，负荷很大，很快就因受力过大而破坏了，因此瓣膜疲劳寿命的测试结果远远小于在体内的实际寿命。这个问题实际是涉及如何保证体外加速实验时人工心瓣结构上所受的载荷与体内生理条件下人工心瓣所受载荷相似的问题。为了使最大应力的分布与生理条件下人工心瓣的最大应力分布相似，我们可以调整循环回路系统的顺应性和阻抗，改变通过瓣膜的流量和跨瓣压差，选择合适的驱动波形驱动直线电机使其按照一定的波形、频率和幅度运动，使心瓣的开闭运动近似生理条件，则加速后系统的运动规律可以接近正常生理条件的规律，瓣后压力波形接近正常生理条件时的主动脉压力波形，瓣膜启闭时不产生水击。

本发明的人工心脏瓣膜疲劳寿命试验装置，它由驱动部分、主体部分、监测部分构成(见图1)。其驱动部分是动力源，它由电源8，任意波发生器9和直流功率放大器10组成。主体部分包括直线电机1实验段2，循环回路30，主轴3，主轴盘4，联杆5及瓣膜架6(见图2.3)。循环回路30采用二单元二参数模型(见图4)，它由气容$C_1$11，$C_2$12，阻尼器$R_1$13，$R_2$14和实验段2组成。瓣膜实验段2各自独立，实验段

2成对的，与主轴3对称分布，本装置采用6个瓣膜实验段。联杆5上端与主轴盘4联接，瓣膜16安装在联杆5下端的瓣膜架6上，由任意波形发生器9产生所需要的波形，经直流功率放大器10放大后，驱动直线电机1通过主轴3，主轴盘4带动联杆5。瓣膜架6向上运动时，在液体惯性作用下瓣膜16打开，当瓣膜架6向下运动时，由于液体阻力使瓣膜16关闭。并推动液体向下运动，液体从每个实验段2流往各自相应的气容$C_1$11和针阀型阻尼器$R_1$13，再汇入储液罐17，该储液罐17中有大气容$C_2$12，其下有带孔隔板18以防水浪，再经可调阻尼器$R_2$14分流返回各实验段。瓣后压力即跨瓣压差通过阻尼器$R_1$13调节，可在0～100mgHg范围内变化，能满足生理的范围。波形发生器9可以提供任意选定的驱动波形，保证直线电机1的运动，使心瓣的开闭运动近似生理条件。通过调整瓣后压力和驱动信号的频率，振幅和波形使加速运行状态下瓣膜16上总载荷曲线接近正常心率下的总载荷曲线，即72次/分心率下的载荷波形(见图6)。直线电机1安装于支架7的上方(见图2)，其结构(见图5)，它由电机轴3(电机轴和主轴为一体)，线圈架19，线圈20，导磁体21，永久磁体22组成，其外部有不锈钢罩23，整个运动部件采用钛合金材料，因此重量轻，频响范围宽，耐疲劳性能好，采用中心导向，径向力小，摩擦小，能耗低，运动平稳，无噪声。

监测系统，包括瓣载测量，瓣膜位移测量和瓣后压力测量三部分。

瓣载测量是用应变式测力传感器24测量瓣膜16在运动过程中所受载荷的变化曲线。该传感器24安装在瓣膜联杆5和主轴盘4的联结处(见图2)，瓣膜16受力通过联杆5传递到测力传感器24上，测力传感器24的输出即为瓣膜16和联杆5，瓣膜架6所受总载荷大小。为了得到瓣膜16所受载荷，必须将联杆5瓣膜架6的动载荷减去，为此我们在调整时首先不装瓣膜16，将两个性能一致的测力传感器24，安装在对称的两个联杆5上，测出不同的频率时瓣膜架6和联杆5的动载荷，

由于完全对称，相减后动载荷为零，然后在一个瓣膜架6上安装被测瓣膜16，另一个不装瓣膜16，在不同频率时两个测力传感器24的输出相减后即得到瓣膜16所受载荷的变化曲线。通过调整瓣后负荷和驱动信号，使在加速运行时载荷接近于正常心率时的载荷。该测力传感器24装拆十分方便，当测力时，将传感器24安装上去，整机调整好后，拆下力传感器24，装置进行正常运行。

压力测量是用血压传感器29，在瓣膜16后实验段2侧壁上开测压孔，经医用小三通阀与实验段2相联接，测得瓣后压力变化。利用医用小三通阀，可使血压传感器29在测压时与实验段2相通，不测压时与大气相通并进行调零。

位移信号的检测：直线电机1的运动是通过位移传感器25测量。该位移传感器25安装在直线电机1的上端(见图2)，采用光电式原理，利用光敏元件所产生的电流与受光面积成比例的原理来检测位移的变化。狭缝光源发出的线光源被直线电机1的轴端遮挡住一部分，照射到光敏元件上，当直线电机1轴端上、下运动时，使光敏元件所感受的光通量发生变化，与直线电机1往复运动的幅度成正比，光敏元件所产生的电流变化即反映了直线电机1振幅变化。该位移传感器25结构简单，无机械传动部件，没有磨损，适合长期连续工作的要求。

本发明的人工心脏瓣膜疲劳寿命的试验装置是在所受载荷接近生理条件下加速，并保证在每次循环中瓣膜16全开全闭。设有观察系统(见图7)。在瓣膜实验段2下方装有反射镜26，用频闪灯28照射在瓣膜16上，调整频闪灯28的闪光频率与瓣膜运动频率有一定的差值时，通过观察筒27可以清楚的看到瓣膜16慢慢打开和关闭过程、是否全开、关闭，瓣膜16是否损坏、变形、瓣叶是否抖动等运动情况，并通过录相系统将其变化情况记录下来。

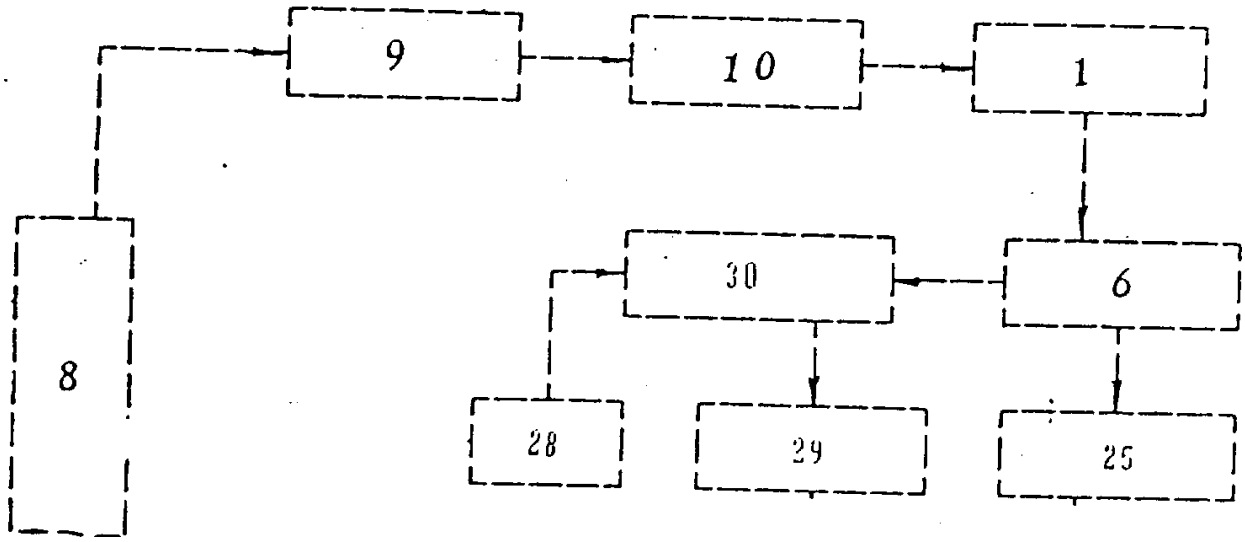


图1

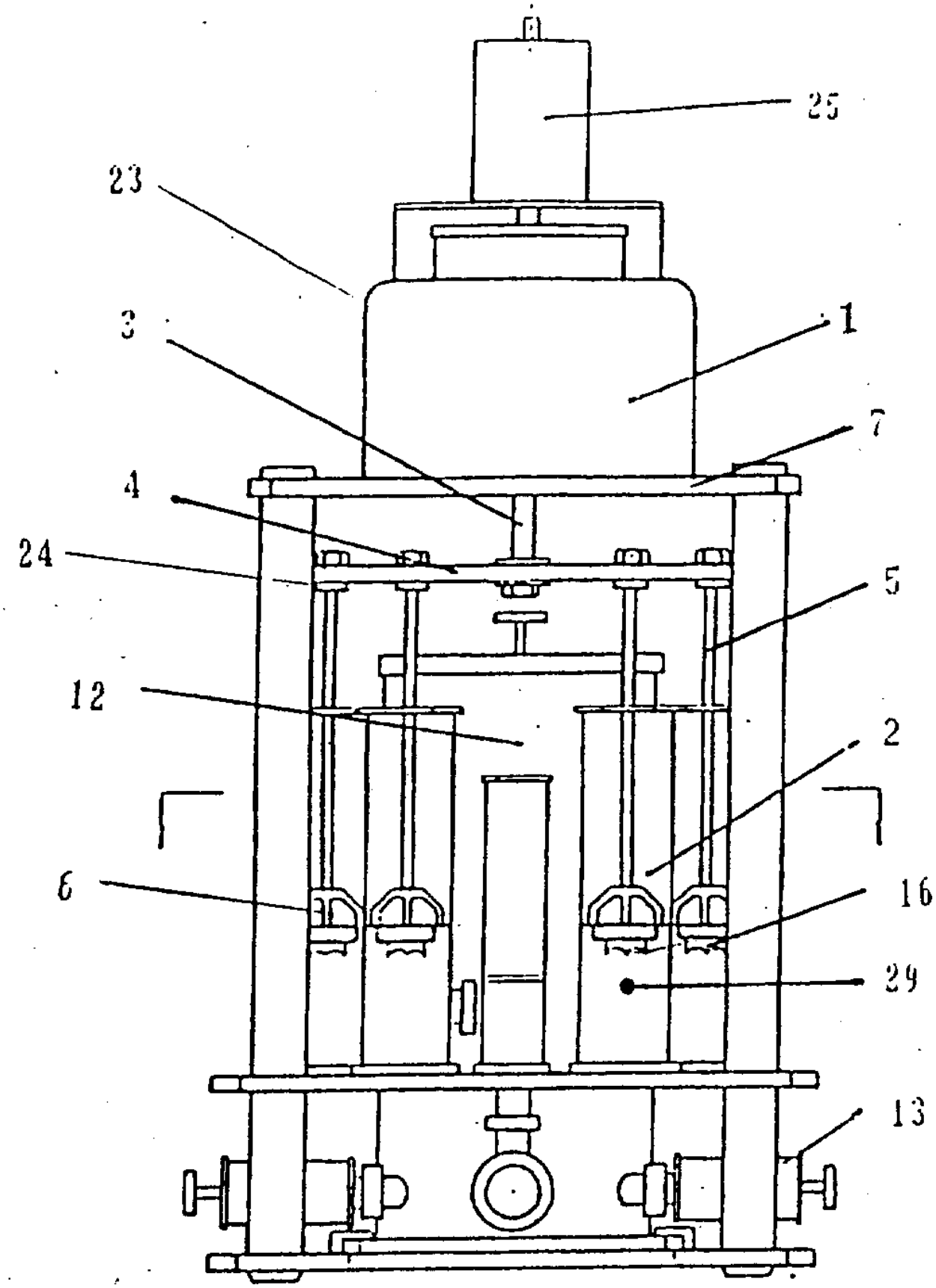


图2

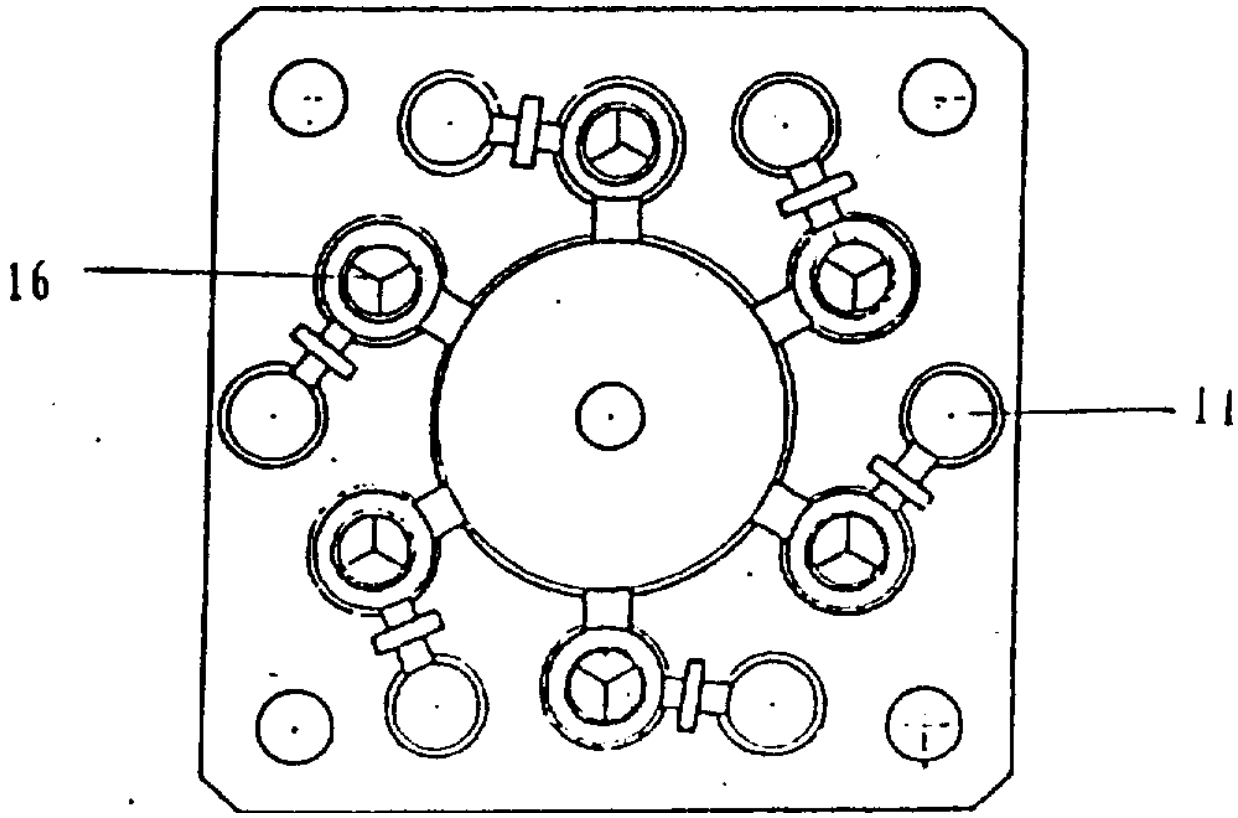


图3

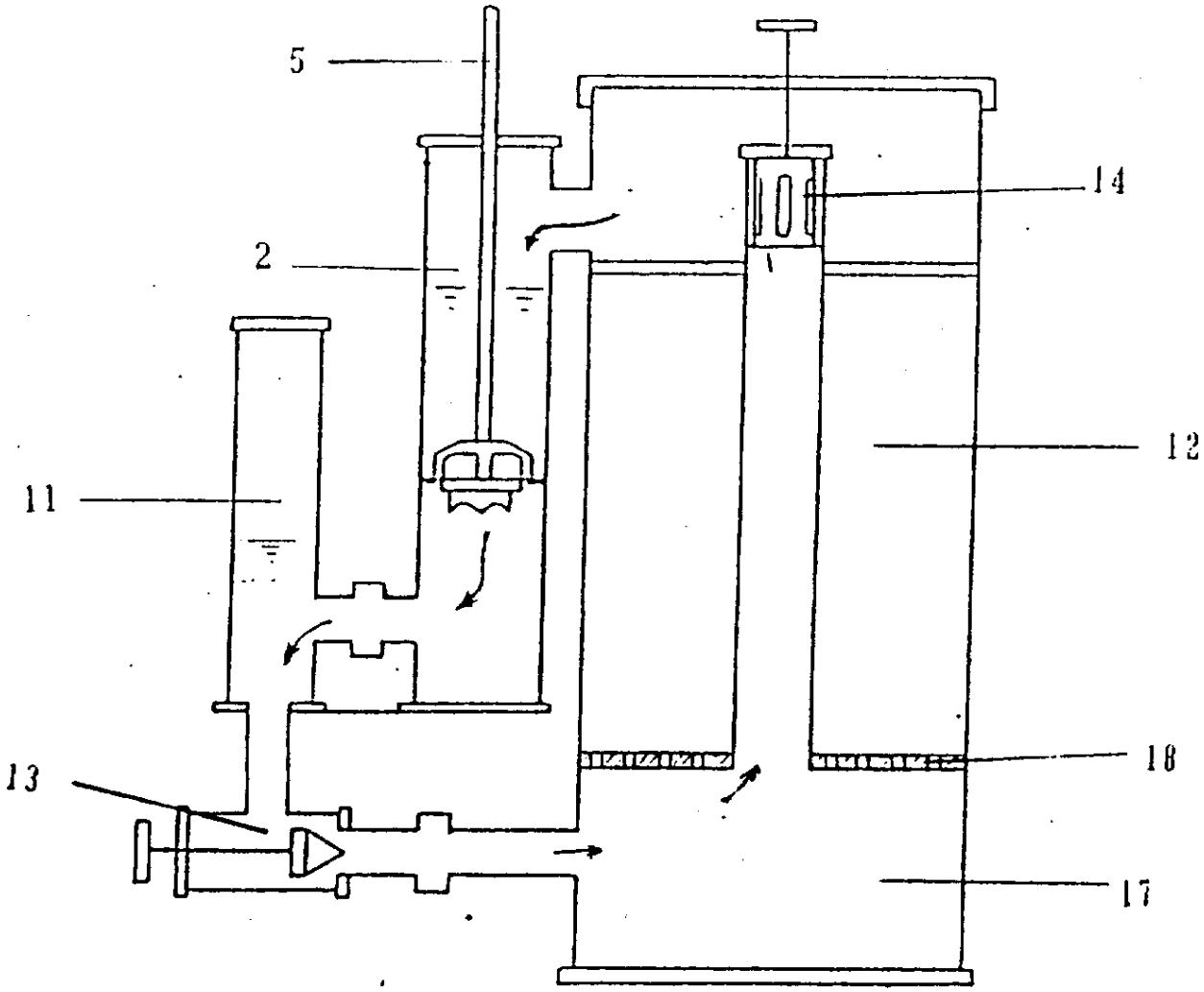


图4

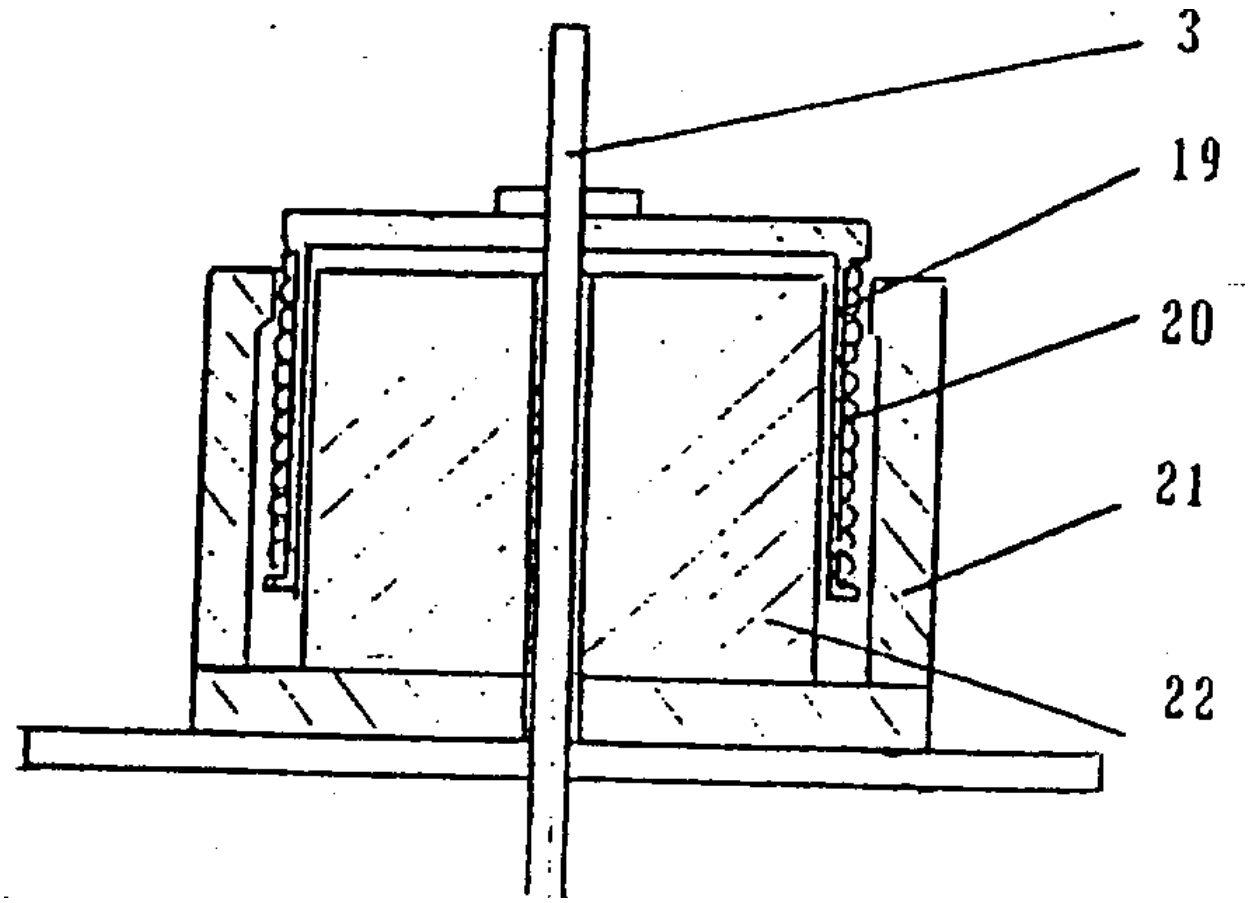


图5

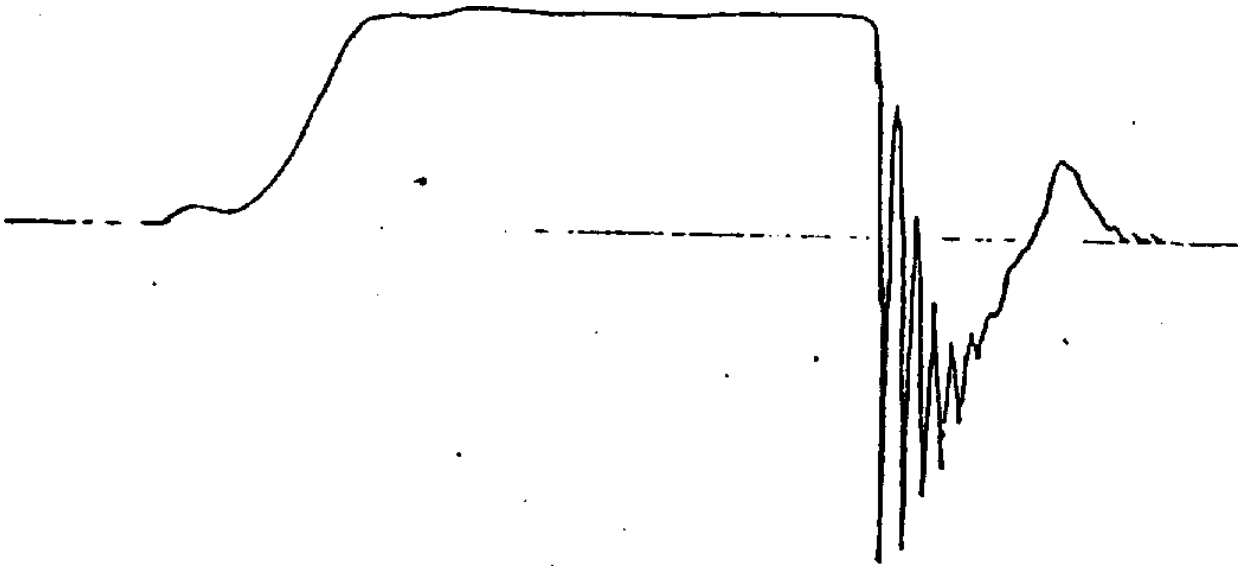


图6

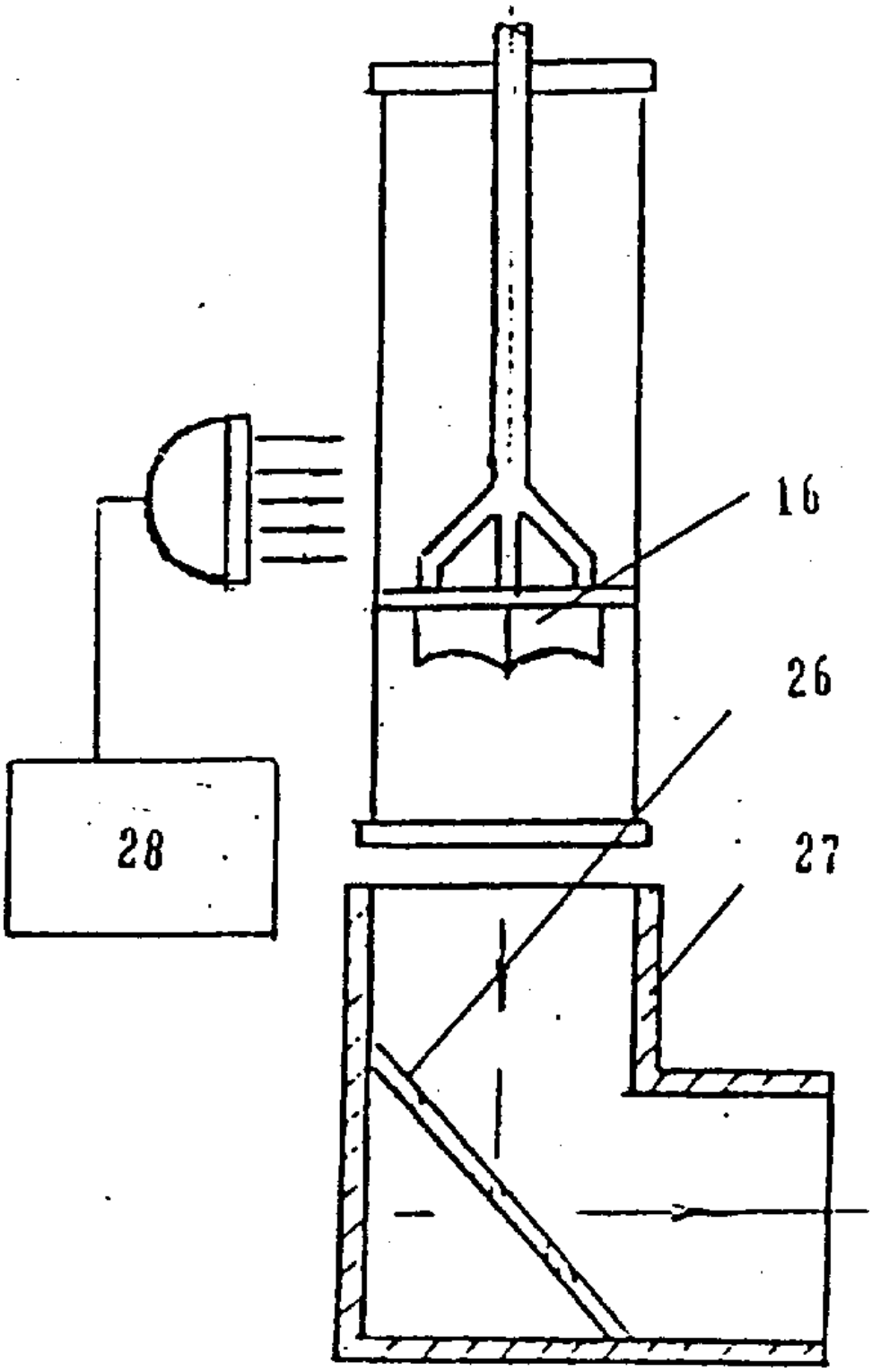


图7